SUSAN S. MUCK (CSB NO. 126930)
DEAN S. KRISTY (CSB NO. 157646)
CHRISTOPHER J. STESKAL (CSB NO. 212297)
CATHERINE D. KEVANE (CSB NO. 215501)
EMILY ST. JOHN COHEN (CSB NO. 239674)
CHRISTINE VOGELEI (CSB NO. 239843)
FENWICK & WEST LLP
555 California Street, 12th Floor
San Francisco, CA 94104
Telephone: (415) 875-2300
Facsimile: (415) 281-1350
smuck@fenwick.com
dkristy@fenwick.com
csteskal@fenwick.com
ckevane@fenwick.com
ecohen@fenwick.com
cvogelei@fenwick.com

Attorneys for Defendants Connetics Corp., John L. Higgins, Lincoln Krochmal, C. Gregory Vontz, and Thomas G. Wiggans

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE CONNETICS CORP. SECURITIES LITIGATION

Case No. C 07-02940 SI

NOTICE OF MOTION AND MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT BY DEFENDANTS CONNETICS CORP., JOHN L. HIGGINS, LINCOLN KROCHMAL, C. GREGORY VONTZ, AND THOMAS G. WIGGANS; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Date: August 15, 2008
Time: 9:00 a.m.
Dept: Courtroom 10
Judge: Honorable Susan Illston

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NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE that on August 15, 2008, at 9:00 a.m. or as soon thereafter as counsel may be heard, in the Courtroom of the Honorable Susan Illston, located at the United States District Court, 450 Golden Gate Avenue, San Francisco, California, defendants Connetics Corp. ("Connetics" or the "Company"), John L. Higgins, Lincoln Krochmal, C. Gregory Vontz, and Thomas G. Wiggans (collectively, "defendants") will and hereby do move for an order dismissing the Second Amended Consolidated Class Action Complaint ("SAC") in this action. Defendants make this motion pursuant to the Private Securities Litigation Reform Act of 1995 ("Reform Act") and Federal Rules of Civil Procedure 12(b)(6) and 9(b) on the grounds that plaintiff has failed to plead facts sufficient to state a claim against them.[1]

ISSUES TO BE DECIDED (CIVIL LOCAL RULE 7-4(A)(3))

1. Whether plaintiff's Section 10(b) claim should be dismissed because:
   a. plaintiff has failed to plead particularized facts demonstrating falsity or scienter;
   b. the forward-looking statements attributed to defendants are protected by the Reform Act's "safe harbor"; and
   c. plaintiff has failed to plead loss causation.
2. Whether plaintiff's claim under Section 20A should be dismissed because:
   a. plaintiff has not shown an underlying violation of Section 10(b);
   b. plaintiff has failed to plead particularized facts demonstrating that any defendant sold Connetics stock on the basis of material non-public information; and
   c. plaintiff has failed to plead that it traded "contemporaneously" with each defendant.
3. Whether plaintiff's Section 20(a) claim should be dismissed because plaintiff has failed to

[1] The motion is based upon the following Memorandum of Points and Authorities, the Request for Judicial Notice In Support of Defendants' Motion to Dismiss Plaintiff's Second Amended Consolidated Class Action Complaint ("Request for Judicial Notice"), the Declaration of Christopher J. Steskal In Support of Defendants' Motion to Dismiss Plaintiff's Second Amended Consolidated Class Action Complaint ("Steskal Decl."), Defendants' Motion to Strike Portions of Plaintiff's Second Amended Consolidated Class Action Complaint and Memorandum of Points and Authorities In Support Thereof, the pleadings and records on file in this case, and such other matters as may be presented to the Court.

allege that defendants committed a primary violation of Section 10(b) or were responsible for or controlled the specific transaction or activity upon which the claim is predicated.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiff fails to address, much less cure, the fundamental pleading deficiencies identified by the Court in its order granting defendants' first motion to dismiss.[2] As detailed in that Order, plaintiff's prior effort fell short because it merely parroted the conclusory allegations of the SEC in a different lawsuit and failed to plead with particularity any facts demonstrating falsity or a strong – *i.e.*, cogent and compelling – inference of scienter. Plaintiff's new effort is largely identical to the prior one. The relatively few additions – principally, superficial references to an "investigation" and a few conclusory statements by new "confidential witnesses" – do nothing to remedy the deficiencies detailed by the Court in its Order.

Faced with those deficiencies, plaintiff now concedes that Velac could be approved by the FDA, but alleges that Connetics and its senior officers committed fraud because, so the argument runs, they all knew that Velac required "additional testing" which would "push out" the approval date. SAC ¶¶ 2-17, 223. Although a significant retreat from its prior theory that Velac "stood virtually no chance of being approved" (AC ¶ 1), plaintiff's new "timing theory" is equally deficient. Plaintiff does not allege any particularized facts demonstrating that anybody – much less the FDA – told defendants that additional testing would be required. In fact, the FDA has approved other acne products subject to ***post-approval*** Phase IV carcinogenicity testing, a fact which eviscerates plaintiff's new theory that any purported need for additional testing would necessarily delay approval. Moreover, this Court has already recognized that even if someone raised concerns about the approvability of Velac, defendants could nonetheless conclude that any such problems were a "surmountable barrier" and that Velac could be approved based on the clinical and preclinical tests that were submitted to the FDA. Order at 14.

Plaintiff's new "timing theory" also fails because it is based on an inherently illogical

[2] *See* Order Granting Defendants' Motion to Dismiss and Defendants' Motion to Strike, Jan. 19, 2008 ("Order").

premise. According to plaintiff, defendants moved full-speed ahead with the time consuming and expensive process of filing a New Drug Application ("NDA"), made a $3.5 million milestone payment to Velac's licensor upon filing the NDA, and spent time and resources in preparing commercial operations to manufacture, distribute, and sell Velac – all the while knowing that the NDA was deficient because it lacked critical data that could only be obtained through additional tests. Not surprisingly, plaintiff's theory is not supported by particularized factual allegations. As with its previous effort, plaintiff has alleged nothing more than impermissible "fraud by hindsight" by attempting to recast the unfortunate story of an unsuccessful effort to obtain approval of a new drug into something nefarious.

Rather than provide particularized facts supported by well-pled allegations, plaintiff resorts to inflammatory and unsupported conclusions. For example, plaintiff's overheated conclusion that "Velac caused cancer" (*see, e.g.*, SAC V.A.3.a) is devoid of any factual support. In fact, the preclinical carcinogenicity test in transgenic mice (the "Tg.AC study") showed that some mice formed papillomas, which are benign skin lesions – not cancerous skin tumors. Likewise, plaintiff now cites a new witness – CW 6 – who was allegedly present during the April 13, 2005 conference call during which an FDA advisory committee allegedly commented on the Tg.AC study. However, CW 6 neither corroborates the alleged statement by the advisory committee that the Tg.AC study raised a "serious issue," nor identifies any defendant as being present during the call. As such, CW 6 negates any inference that defendants intended to mislead investors when Connetics voluntarily disclosed that the FDA had raised an issue with respect to the Tg.AC study for the first time.

Nor has plaintiff offered any response to the Court's call to provide the basic who, what, when, and where of the purported financial fraud. This Court dismissed plaintiff's prior effort at alleging financial fraud because its complaint contained "no details as to specific shipments, customers, times, or dollar amounts relating to the alleged channel stuffing," but rather was based on the legally incorrect proposition that the mere fact of a restatement is enough to plead a strong inference of scienter. Order 19-20. Plaintiff's new complaint is no better. Despite this Court's prior ruling, plaintiff still has not identified a single transaction — much less one with any

particularity — that it alleges involved channel stuffing, nor has it shown that each defendant knew (or was deliberately reckless in not knowing) that Connetics' reserves were inadequate at the time Connetics issued its financial statements. Because such allegations are again entirely absent, plaintiff's complaint should be dismissed again, but this time with prejudice.

II. STATEMENT OF FACTS

A. Factual Background

1. Connetics And The Moving Defendants

Connetics was a specialty pharmaceutical company that developed and marketed drugs for the dermatological market. SAC ¶ 1.[3] During the purported class period from January 27, 2004 to July 9, 2006, Connetics offered four products and had several products in development, including Velac Gel. *Id.* ¶¶ 4, 226-227. Tom Wiggans served as Connetics' Chief Executive Officer and a member of the Board of Directors; Greg Vontz was Chief Operating Officer and was promoted to President in February 2005; John Higgins was Executive Vice President, Finance and Administration and Corporate Development; and Dr. Lincoln Krochmal was Executive Vice President of Research and Product Development. *Id.* ¶¶ 34-37.

2. The FDA Approval Process

The FDA approval process is "lengthy, expensive and uncertain." Ex. 6, at 22 (Form 10-K); Ex. 7, at 31 (Form 10-K/A).[4] According to the FDA's published data, approximately 40% of new drug candidates are not approved. Ex. 44, at 14, 16. Connetics repeatedly described the risks associated with new drug development and cautioned investors that "[s]uccessful product development in our industry is highly uncertain" and that "[v]ery few research and development products produce a commercial product." Ex. 6, at 23.

To obtain FDA approval, a drug sponsor must demonstrate that the new drug candidate is "safe and effective" for human use.[5] 21 C.F.R. § 314.2. To that end, the FDA requires the drug

[3] In December 2006, Connetics was acquired by Stiefel Laboratories, Inc. in a $640 million merger and is no longer a publicly-held corporation.

[4] All references to exhibits are to those attached to the Steskal Decl. and will appear in the form "Ex. __." The Court may consider all such exhibits because they are either cited or quoted in the SAC or are otherwise subject to judicial notice. *See* Request for Judicial Notice filed herewith.

[5] By law, the FDA does not require sponsors to prove that a new drug will be 100% safe and

sponsor to conduct both preclinical and clinical tests. SAC ¶ 62. The basic purpose of preclinical tests is to gather enough information through laboratory experimentation and animal tests to determine whether the drug is sufficiently safe for trials in humans. 21 C.F.R. § 312.23(8); Ex. 6, at 10. The results of the preclinical tests are submitted to the FDA, and if the FDA determines that the drug is sufficiently safe for human trials, it will authorize Phase I clinical testing on humans. 21 C.F.R. §§ 312.22, 312.23.

Phase I tests are conducted on a small group of patients and are designed to assess the safety of a drug in humans. *Id.* § 312.21. Phase II studies, which are conducted on a larger patient population, assess a drug's efficacy and continue the human safety analysis. *Id.* Finally, Phase III studies are conducted on yet a larger group and are designed to definitively determine a drug's safety and effectiveness. *Id.* The FDA closely monitors each phase of clinical trials and will only approve the next phase if the results from the previous phase demonstrate that it is safe to do so. *Id.* §§ 312.21, 312.22. The FDA has the authority to suspend clinical testing on humans if, at any point, it determines that the drug is not sufficiently safe for human use. *Id.* § 312.42.

After clinical testing, the sponsor submits an NDA to the FDA. *Id.* § 314.1. Prior to submitting the NDA, the sponsor meets with the FDA to discuss major unresolved problems. *Id.* § 312.47. The FDA will only accept an NDA for filing if it determines that the data is sufficient. Ex. 52, at 10. After accepting an NDA, the FDA is required by statute to act on it within a specified period of time, the so-called "PDUFA date." *Id.* § 314.100.

Throughout the review process, the FDA engages in frequent formal and informal communications with the drug sponsor. The FDA review process is intended to be collaborative and iterative. *Id.* § 314.102. Formal communications include the so-called 74-day letter (due 74 days after an NDA is filed) in which FDA officials are required to communicate any substantive deficiencies identified during the initial filing review. *See* Ex. 26, FDA Manual of Policies and Procedures for the Center for Drug Evaluation and Research ("FDA Manual") § 6010.5. Informal communications continue throughout the review process to address scientific,

effective. Ex. 52, at 10 (Congressional Research Service Report, The U.S. Drug Approval Process: A Primer (2001)) ("CRS Report"). Instead, the FDA looks at the totality of the data regarding a drug's safety and efficacy and does a benefit to risk analysis. *Id.*

medical, and procedural issues that may arise during the on-going FDA review. 21 C.F.R. § 314.102.

After a sponsor submits an NDA, several groups within the FDA review it and prepare written reports containing their recommendations. *See* Exs. 28, 29. Those reports are then evaluated by the division director, who is ultimately responsible for making an approvability decision. *Id.* The division director may also consult with advisory committees established by the FDA. *Id.* The director reviews the various reports and recommendations of the divisions and advisory committees, but is not bound by them. *See id.*; Ex. 27, FDA Manual § 7412.2

The director may take one of several actions with respect to an NDA, only one of which involves an outright denial of the NDA:

- The director may **approve** the drug outright;
- The director may **approve the drug with labeling requirements**, *i.e.*, with a warning for patients and physicians;
- The director may **approve the drug with post-approval Phase IV testing**, *i.e.*, with a requirement that the sponsor conduct additional testing either in animals or on humans; or
- The director may refuse to approve the drug.[6]

3. The Preparation Of The Velac NDA

Velac was a "novel, first in class, dual-active product combining the anti-inflammatory and antibiotic effects of clindamycin with the beneficial effects of tretinoin." Ex. 8; *see also* SAC ¶¶ 68-69. Clindamycin and tretinoin are among the most widely prescribed medications for acne. *Id.* ¶ 69. Velac successfully combined these active ingredients for the first time. *Id.* Connetics licensed the United States rights to Velac from Yamanouchi Europe B.V. in May 2002. *See id.* ¶ 68. At that time, Velac had already undergone extensive testing. European clinical studies involving more than 700 patients had demonstrated that Velac was both safe and effective. Ex. 8.

From May 2002, Connetics worked with the FDA to complete the testing required to file an NDA. Because Velac had already been extensively tested on humans during the European clinical trials, the FDA permitted Connetics to conduct clinical trials in the United States at the

[6] 21 C.F.R. §§ 314.102, 314.110, 314.105, 312.852.

same time that it performed preclinical tests. Connetics disclosed to investors both the status of the Velac NDA application and the results of its clinical trials:

- In May 2002, Connetics announced its plan to request a pre-NDA meeting with the FDA. Ex. 8.
- In March 2003, Connetics announced that the FDA approved conducting Phase III clinical trials in December 2002. SAC ¶ 77.
- In late 2003, Connetics announced that it had completed enrollment in the clinical trials. *Id.* ¶ 78.
- In March 2004, Connetics announced the excellent results of Phase III clinical trials and that Velac had been approved for commercial sale in Europe. *Id.* ¶ 80; Ex. 6, at 6.

Whenever it commented on the regulatory status of Velac, Connetics cautioned investors about Velac's uncertain prospects for approval. Ex. 10 (Form 8-K). In its public statements, Connetics warned that it "faces risks and uncertainties that . . . ***Velac may not be approved by the FDA in the timeframes projected, if at all***" (Ex. 11 (Form 8-K) (emphasis added)), and that its efforts with respect to Velac "***may not result in the successful introduction of a new product.***" (Ex. 6, at 5 (Form 10-K) (emphasis added)). Connetics also cautioned investors that "product candidates that appear promising in the early phases of development may not reach the market for a number of reasons," including "because the ***FDA has substantial discretion in the approval process***" and "***may not interpret our clinical data the way we do***." Ex. 3, at 18; Ex. 4, at 20; Ex. 5, at 24; Ex. 6, at 23 (Forms 10-K).

4. The Tg.AC Mouse Study

In preparation for filing its NDA, Connetics conducted a pre-clinical carcinogenicity study using Tg.AC mice from January 2004 through June 2004. SAC ¶ 7. Although the FDA requires animal testing as part of the NDA application, different species are used for different types of tests. The FDA and the sponsor discuss the scope and conduct of the animal testing, including the species to be tested and the results to be tested for. Carcinogenicity tests, for example, can be performed using "normal" rats or mice, or transgenically altered Tg.AC mice. The Tg.AC study, while faster than one conducted on a normal mouse, has significant limitations and does not

always or reliably predict risks to humans.[7] Indeed, in light of the strong results of the European clinical trials, the FDA permitted Connetics to conduct Phase III clinical testing on over 2,200 patients in parallel with the Tg.AC study, which was an indication to Connetics that the outcome of clinical studies on humans, rather than the Tg.AC study, would be central to the FDA's decision. There is no dispute that the results of Phase III clinical testing were excellent. Ex. 10.

Plaintiff has nothing to say about the excellent Phase III clinical results. Instead, plaintiff alleges that the Tg.AC mouse study showed that "89 out of 160 of the mice (approximately 56%) treated with Velac developed cancerous skin tumors." SAC ¶ 92. That allegation is based entirely on a single sentence in a complaint filed by the SEC in a different civil lawsuit against ***other*** parties.[8] According to the SEC complaint, a certain number of mice treated with Velac gel "in varying formulations and dosages . . . developed tumors."[9] Neither the plaintiff in this lawsuit nor the SEC pleads any factual detail about the Tg.AC test results, including the dosage, length of exposure, or concentration levels used in the study. Likewise, the sentence cited by plaintiff does not support the allegation that Velac caused cancer, rather than benign skin lesions called papillomas.

Putting aside plaintiff's failure to set forth any corroborating detail to support its allegations relating to the Tg.AC study, plaintiff also fails to account for the fact that Connetics (and the investing public) were aware of numerous dermal products that the FDA approved despite positive responses in carcinogenicity studies.[10] In fact, tretinoin – one of Velac's active ingredients – is a known carcinogen, but nevertheless is commonly included in a number of FDA

[7] AC ¶ 56 (Tg.AC mouse model fails to make "the correct calls" in significant number of cases); Ex. 48, at 3 ("important issues of validation and standardization need further attention to permit their regulatory acceptance and use in human risk assessment"). The Court can consider allegations in the earlier complaint in ruling on this motion to dismiss. *See Azadpour v. Sun Microsystems, Inc.*, 2007 U.S. Dist. LEXIS 55502, at *6 n.2 (N.D. Cal. July 22, 2007).

[8] Neither Connetics nor any of its senior officers is a party to the SEC's lawsuit. The district court in the Southern District of New York where the SEC suit is pending has held that this lawsuit is unrelated to the SEC's suit. *See* Ex. J. to Declaration of Dean S. Kristy In Support of Motion to Transfer Venue, filed in this action March 2, 2007.

[9] *See* Declaration of Christopher J. Steskal In Support of Motion to Strike, Ex. 1 ¶ 20.

[10] Many of these drugs was approved by the same division director responsible for reviewing Velac. *See* Ex. 35 (Differin Approval Ltr.); Ex. 41 (Aldara Approval Ltr.); Ex. 37 (Retin-A Approval Ltr.); Ex. 39 (Protopic Approval Ltr.); Ex. 33 (Duac Approval Ltr.); Ex. 31 (BenzaClin Approval Ltr.).

approved acne medications. *See, e.g.*, Ex. 36 (Retin-A label); *see also* SAC ¶ 70. In addition, BenzaClin and Duac were approved with post-approval Phase IV carcinogenicity testing requirements. Ex. 31 (BenzaClin Approval Ltr.); Ex. 33 (Duac Approval Ltr.). Both products contain benzoyl peroxide, which is a common ingredient in many acne medications. The FDA-approved labeling for both products state:

> Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week ***induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment***.

Ex. 30, at 6 (BenzaClin Label); Ex. 32, at 5 (Duac Label) (emphasis added). Moreover, the labels for four other dermatological products – Differin, Retin-A, Protopic, and Aldara – demonstrate that the FDA approved each despite positive responses in carcinogenicity studies, including (for Aldara) a positive response from its vehicle:

- "[I]ncreased incidence of benign and malignant pheochormocytomas in the adrenal medullas of male rats was observed." Ex. 34, at 4 (Differin Label).
- "[C]utaneous squamous cell carcinomas and papillomas in the treatment area were observed in some female mice" as well as "[a] dose-related incidence of liver tumors in male mice . . ." Ex. 36, at 2 (Retin-A Label)
- "[A] statistically significant elevation in the incidence of pleomorphic lymphoma in high dose male (25/50) and female animals (27/50) and in the incidence of undifferentiated lymphoma in high dose female animals (13/50) was noted in the mouse dermal carcinogenicity study." Ex. 38, at 11 (Protopic Label) (emphasis added).
- "In a dermal mouse carcinogenicity study . . . [a]n increased number of skin papillomas was observed in ***vehicle cream*** control group animals at the treated site only." Ex. 40, at 9 (Aldara Label) (emphasis added).

Connetics consulted a panel of experts regarding the Velac NDA and the Tg.AC test results. The panel concluded that Velac's positive response in the Tg.AC mouse model was a result of a limitation in the model, *i.e.*, it was a false positive. SAC ¶ 260. There is no dispute that Connetics included the Tg.AC study and the expert panel's analysis of that study in the Velac NDA. Given the inherent limitations of the Tg.AC mouse model, the FDA's approval of other dermal products with positive responses in that model, and the fact that the FDA had not raised any concerns with Connetics about the pre-clinical test results in the pre-NDA meeting, 74-day letter, or otherwise, defendants were optimistic about Velac's prospects for approval by the

PDUFA date. And Connetics acted in accordance with its belief.

- Connetics incurred substantial time and expense to prepare and file the NDA for Velac in August 2004. SAC ¶ 250; Ex. 12 (Form 8-K); Ex. 6, at 6 (Form 10-K).
- Connetics paid an additional $3.5M to Yamanouchi as a milestone payment for its Velac license, triggered by filing the NDA. SAC ¶ 223; Ex. 6, at 34, 36 (Form 10-K).
- Connetics began preparing its commercial operations for the launch of Velac in 2005, including, for example, hiring more than 60 new sales professionals in January 2005 as part of a sales force expansion. SAC ¶ 241 Ex. 13 (Form 8-K).

These actions confirm that Connetics was optimistic about the future approval of Velac and was making plans and spending money accordingly; they destroy the notion that defendants knew "all along" that the Velac NDA was deficient and that Velac would not be approved without additional testing.

5. Communications With The FDA Regarding The Velac NDA

In August 2004, Connetics filed the Velac NDA with the FDA, and in October 2004, the FDA accepted the NDA. *See* SAC ¶¶ 224-27; Ex. 12 (Form 8-K). The FDA set a PDUFA date of June 25, 2005. SAC ¶ 5. Plaintiff does not allege that the FDA raised any concerns with respect to Velac or the Tg.AC study at any time prior to or during the eight-month period following the filing of the NDA. It does not allege that the FDA told Connetics that the Tg.AC study foreclosed or would delay FDA approval of Velac during the pre-NDA meeting. Nor does it allege that the FDA raised the issue in its 74-day letter sent to Connetics in November 2004. In fact, plaintiff still fails to allege any facts suggesting that the FDA, despite its broad powers to comment, halt clinical trials, issue warning letters, or otherwise identify problems or deficiencies, gave Connetics any indication that the Velac approval process was not on track or that it had any negative views about Velac or any of the information Connetics supplied in support of its NDA.

Plaintiff thus admits, as it must, that the first time the FDA expressed any concern about the Tg.AC study was on April 13, 2005, sixteen months into the putative class period. SAC ¶¶ 108-110. On that date, plaintiff alleges that there was a conference call with the Executive Carcinogenicity Assessment Committee ("ECAC"), an advisory committee to the FDA. Plaintiff cites the SEC complaint for the proposition that "ECAC told Connetics . . . that Velac may be a tumor promoter or a carcinogen," and that "this is a serious issue for a topical product for the

treatment of acne." *Id.* However, according to a "confidential witness" who allegedly attended the meeting, what was actually said to Connetics was that "the Mouse Study results 'may be a problem.'" SAC ¶ 43(f).

In any event, plaintiff does not contest, nor can it, that all ECAC reports are advisory in nature and clearly state that they "***should not be interpreted by the sponsor as a measure of the approvability of their application***" (emphasis added). Ex. 27 (FDA Manual § 7412.2) (emphasis added).[11] Nevertheless, Connetics voluntarily provided on Form 8-K, which is filed to alert investors of the possibility of material developments, an update on the status of the Velac program:

> Over the past several weeks Connetics has been responding to the [FDA's] questions regarding the Company's New Drug Application ("NDA") for its product candidate Velac. As part of this dialogue, the Company recently received communications from the FDA indicating that the agency was interpreting some of the results of a pre-clinical study for Velac® Gel differently than the Company did in the NDA submission. The preclinical study in question involved a transgenic mouse model. In the study, there was a positive response to the product. The Company carefully analyzed the results with a panel of leading toxicologists and experts in this model. The experts advised the Company that the transgenic mouse model is known to have limitations, and the experts concluded that the positive response was the result of a limitation of the model. The advice of these experts is supported by other products which had a positive finding but were ultimately approved based on additional work in other animal models. The Company is continuing its discussions with the FDA and expects to submit additional information which further supports the Company's original conclusion.

SAC ¶ 260; *see also* Ex. 15 (Form 8-K).[12] In response to these disclosures, analysts projected delays of up to one year for Velac and/or reduced their revenue estimates.[13] Thus, the market understood from these disclosures that there was potentially a "serious issue" affecting the timing or approvability of Velac based on the FDA's recent comment.

After the April 26, 2005 voluntary disclosure on Form 8-K, Connetics prepared

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[11] In fact, the very same FDA division director making the determination on Velac had previously approved dermatology products, such as Clobex, notwithstanding similar "safety" concerns of the FDA advisors. *See* Exs. 30, 32, 34, 36, 38, 40 (publicly available FDA director review and approval letters).

[12] Connetics provided a similar summary of the status of the Velac program during an analyst call on the same day. Ex. 1, at 5-6 (analyst call transcript).

[13] Ex. 45 (Wachovia Capital projects delay of one year on April 26, 2005); Ex. 46 (Jeffries & Co. pushes launch date back six months); Ex. 47 (Summer Street projects delay of one quarter, with 12-18 months possible).

submissions to the FDA to address the FDA's newly-raised concerns with the Tg.AC study. Ex. 1, at 6. After the close of market on Friday, June 10, 2005, while the Company was in the process of submitting additional data to the FDA in support of its application, Connetics received a non-approvable letter for Velac. SAC ¶ 128. That letter came two weeks before the PDUFA date and without prior notice by the FDA. *Id.* Before the market opened on June 13, Connetics disclosed that the FDA had not approved Velac. *Id.* ¶ 129.

6. Connetics' Financial Restatement

Connetics' FDA-approved products are not sold directly to patients or doctors, but instead are sold through wholesale distributors. *Id.* ¶ 149; Ex. 7, at 14 (Form 10-K/A). These distributors in turn sell to retail pharmacies. SAC ¶ 149. During the class period, Connetics had agreements with three main distributors that accounted for the overwhelming majority of its sales – Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Corporation. *Id.* Under these agreements, these distributors agreed to provide inventory level reports which Connetics could use to forecast future demand for its products. *Id.*

The ability to forecast future demand is among the important variables in calculating reserves. *See* SAC ¶¶ 155, 165; Ex. 18 (Form 8-K). Reserves are used to account for future estimated rebates, chargeback, and returns. SAC ¶¶ 151-54. For example, when state and local Medicare programs purchase Connetics products, Connetics is required to pay a rebate under the Federal Medicaid Rebate program. *Id.* Although Connetics is not billed for the rebate until a patient purchases the drug from a pharmacy, the rebate obligation arises when Connetics sold the drug to the distributor, requiring Connetics to "predict" at the time of sale what percentage of product would be purchased through the Medicare program. As another example, distributors and pharmacies have certain rights to return Connetics products that are within one year of their expiration date. *Id.* Connetics sets aside accruals and allowances, which are estimates of the age of the product a distributor or pharmacy may hold, to meet these obligations. *Id.* ¶ 155. As Connetics publicly disclosed, various other factors are also important in calculating the reserves, including timing and terms of plans under contract, time to process rebates, product pricing, sales volumes, units held by distributors, and prescription trends. Ex. 18 (Form 8-K); Ex. 5, at 39-40

(2003 Form 10-K); Ex. 6, at 37-38 (2004 Form 10-K).

On May 3, 2006, Connetics announced that it would be restating its 2005 financial statements (and potentially earlier periods) by approximately $8-9 million due to the insufficiency of certain of its reserves. SAC ¶ 177. Following this announcement, Connetics' stock price *increased*. Ex. 51 (stock prices). On July 25, 2006, after the class period, Connetics filed its amended Form 10-K for the year ended December 31, 2005 that included restated financials for 2004 and 2005. SAC ¶ 185. As a result, net revenue in 2004 was reduced from $144.4 million to $143.2 million (with net income reduced from $19 million to $17.9 million), and net revenue in 2005 was reduced from $184.2 million to $176.3 million (with net income reduced from $33.9 million to $26.1 million). *Id.*[14]

B. Procedural Background

In its Order granting defendants' motion to dismiss, the Court held that plaintiff had failed to set forth an adequate basis for any allegation that was taken "directly from the SEC complaint with no additional investigation," including the allegations relating to the Tg.AC study and certain alleged statements by members of the expert panel. Order at 10. The Court also held that even if those allegations were considered, plaintiff had failed to allege facts creating a strong inference of scienter with respect to forward-looking statements. *Id.* at 14. Those statements "were not made in the face of actual knowledge that Velac could never be approved; rather they may have been made in the optimistic belief that the transgenic testing problem was a surmountable barrier to FDA approval." *Id.* The Court held that after striking the allegations that were based on the SEC complaint, plaintiff had not adequately pled facts demonstrating that any other statement relating to Velac was actionable. *Id.* at 14-18. The Court next addressed plaintiff's allegations regarding the financial statements, holding that the fact of a restatement

[14] As explained in the restatement, Connetics had been estimating its return rate based on cumulative historical return experience rather than the most recent three years' data, and it had been calculating the value of the estimated returned products based on the original sales price rather than the price following any price increases. In addition, Connetics' reserve estimates were impacted by inaccurate and inconsistent inventory level reports provided by its three main wholesale customers. Ex. 7, at 31, 43-44 (Form 10-K/A). Once Connetics began to receive accurate reports, it was able to conclude that its product inventory at these wholesalers was higher than previously estimated, and accordingly took steps to increase its reserves. *See id.*

alone is insufficient to establish scienter and that plaintiff's allegations were "completely lacking in any specific details." *Id.* at 19.

III. LEGAL STANDARDS

With the enactment of the Reform Act, Congress imposed new and more stringent pleading standards on class actions filed under the 1934 Act in order to deter "abusive securities fraud claims." *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 973 (9th Cir. 1999); *In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1084-85 (9th Cir. 2002). The Ninth Circuit has emphasized that "[t]he [Reform Act] requires a plaintiff to plead a complaint of securities fraud with an unprecedented degree of specificity and detail . . . . This is not an easy standard to comply with – it was not intended to be – and plaintiffs must be held to it." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003). These heightened requirements are binding on all claims in the SAC. *See* 15 U.S.C. § 78u-4(a)(1).

The Reform Act demands that plaintiffs identify precisely "each statement alleged to have been misleading, [and] the reason or reasons why [it] is misleading." 15 U.S.C. § 78u-4(b)(1)(B). Particularized facts must therefore be pled to show "the who, what, when, where, and how of the misconduct charged" for each allegedly fraudulent misstatement, on a defendant-by-defendant basis. *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (quoting *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997)); *In re Silicon Storage Tech., Inc. Sec. Litig.*, 2006 WL 648683, at *3 (N.D. Cal. Mar. 10, 2006).

Pleadings must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2); *Silicon Graphics*, 183 F.3d at 974. In its recent *Tellabs* decision, the Supreme Court adopted a stringent test for pleading scienter. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509-10 (2007). When reviewing plaintiff's allegations of scienter, the court "must consider plausible nonculpable explanations for the defendant's conduct . . . . [An] inference of scienter must be more than merely 'reasonable' or 'permissible' – it must be cogent and compelling, thus strong in light of other explanations." *Id.* at 2510. And it must be "at least as compelling" as any contrary inference. "A complaint will survive, we hold, only if a reasonable person would deem the

inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

A complaint failing to meet all of these heightened requirements must be dismissed. *See* 15 U.S.C. § 78u-4(b)(3)(A). Moreover, as *Tellabs* makes plain, in assessing a complaint's sufficiency, inferences *unfavorable* to plaintiff must be considered. *See Tellabs*, 127 S. Ct. at 2511 ("omissions and ambiguities count against inferring scienter"); *see also Gompper v. VISX Inc.*, 298 F.3d 893, 897 (9th Cir. 2002). In short, "[i]n few other areas are motions to dismiss . . . so powerful" as under the Reform Act. *Ronconi v. Larkin*, 253 F.3d 423, 437 (9th Cir. 2001).

IV. PLAINTIFF'S MINOR REVISIONS TO ITS PRIOR VELAC-RELATED CLAIMS FAIL TO CURE THE FUNDAMENTAL DEFECTS IN THEIR ALLEGATIONS OF SCIENTER AND FALSITY

A. Plaintiff Again Fails To State A Claim With Respect To Forward-Looking Statements

1. Plaintiff Cannot Plead Facts Creating A Strong Inference That Defendants Had Actual Knowledge of Falsity

Plaintiff continues to base its claim on patently forward-looking statements about Velac's prospects for approval, including the following:

- "***Looking ahead, we are … preparing*** our commercial operations for the introduction of Actiza, Extina and Velac." SAC ¶ 223 (emphasis added);
- "Connetics ***projects*** it will make a $3.5 million milestone payment to Yamanouchi Europe B.V. in the third quarter concurrent with the ***projected*** submission of the Velac NDA." *Id.* (emphasis added);
- "[We] are confident that ***we will be*** successful in this market with our acne franchise, and in particular, with Velac." *Id.* ¶ 241 (emphasis added); and
- "[W]e ***expect*** [Velac] to be launched midyear." *Id.* ¶ 242.

As this Court has already held, plaintiff cannot state a claim with respect to such forward-looking statements unless it pleads particularized facts "creat[ing] a **strong inference** that defendants had **actual knowledge of falsity** at the time their predictions about Velac were made . . . ." Order at 14 (emphasis added); *see also* 15 U.S.C. § 78u-5(c)(1)(B) (requiring actual knowledge of falsity for forward looking statements). Plaintiff cannot meet that standard here. To the contrary, defendants had ample reason to be optimistic about Velac's future approval,

including: (1) the outstanding results of the clinical trials involving thousands of human patients (both in the U.S. and Europe); (2) the fact that the FDA had approved other dermal products that tested positive in the Tg.AC mouse model and similar carcinogenicity studies (*e.g.*, BenzaClin, Duac, Differin, Retin-A, Aldara, Protopic); (3) the approval of Velac in Europe; (4) the lack of any adverse comments by the FDA during the pre-NDA process, in the 74-day letter, or at any time prior to April 13, 2005; and (5) the number of false positives associated with the Tg.AC mouse test and the conclusion of the expert panel that Velac's test results were a false positive.

Recognizing the fatal flaw in its earlier complaint, plaintiff now concedes that Velac could have been approved, but alleges that "the positive Mouse Test meant that the FDA would – at the very least – require the Company to run additional testing" and that "this additional testing would push out approval by many months if not years." *See, e.g.,* SAC ¶ 233. However, plaintiff never alleges that defendants were informed that additional testing would be required or that they actually drew such a conclusion. In fact, defendants were aware that the FDA had approved other acne drugs that had tested positive in the Tg.AC model (such as, BenzaClin and Duac), requiring only ***post-approval*** Phase IV carcinogenicity testing and labeling. *See supra* at 9-10. As this Court has already recognized, the fact that other acne drugs that tested positive in the same test had been approved without delay eviscerates any allegation of scienter here. Order at 14; *see also In re Vertex Pharms. Inc. Sec. Litig.*, 357 F. Supp. 2d 343, 352 (D. Mass. 2005) ("Defendants note that other drugs (such as Lipitor and Zocor) have been found in animal studies to have toxic effects . . . yet have been approved by the FDA. Thus defendants' knowledge of some toxicity in VX-745 in 1999, without more, is insufficient to indicate a mental state embracing intent to deceive, manipulate, or defraud.") (internal citation omitted).

Plaintiff's "timing theory" also fails because it is utterly devoid of the factual particularity required by *Tellabs*. As alleged by plaintiff, the claim is based on the opinion of an alleged former member of the expert panel ("CW 5"). However, that opinion is unrelated to Velac, hypothetical in nature, and formed with the benefit of hindsight. SAC ¶ 43(e). In fact, nothing in the SAC establishes that CW 5 or anyone else ever expressed an opinion to defendants regarding the need for additional testing, much less when it was communicated or whether defendants or

other participants on the panel shared the opinion. The law is clear that plaintiff cannot base its claim on such an allegation.[15] *See Silicon Graphics*, 183 F.3d at 985 (holding that "[i]n the absence of such specifics, we cannot ascertain whether there is any basis for the allegations that the officers had actual or constructive knowledge of [the alleged] problems that would cause their optimistic representations to the contrary to be consciously misleading"); *Tripp v. Indymac Fin. Inc.*, 2007 WL 4591930, at *3 (C.D. Cal. Nov. 29, 2007) (dismissing claim where plaintiffs "failed to allege that the individual Defendants shared these beliefs and opinions or even that they were aware of them and found them to be reliable and justified").

Moreover, as this Court has already held, defendants could be optimistic about Velac's prospects for approval irrespective of any "concerns expressed by their panel of experts." Order at 14. That is true because "defendants had not heard anything from the FDA indicating that the FDA had concerns" and "defendants were aware of another drug that had been approved by the FDA despite a positive transgenic test." *Id.* If the alleged concerns of the entire panel are insufficient to create a strong inference of scienter, then the alleged opinion of a single panel member regarding the need for additional testing is plainly insufficient. As this Court recognized, defendants' statements regarding the future approval of Velac "may have been made in the optimistic belief that the transgenic testing problem was a surmountable barrier to FDA approval." *Id.*[16] Indeed, contrary to plaintiff's allegations, and as this Court has already held, the law is clear that adverse information arises routinely in the course of seeking approval of a new

[15] Plaintiff's allegations relating to CW 6 fare no better. According to the SAC, CW 6 was "a former Connetics Senior Manager of Regulatory Affairs" who "had not previously worked on Velac but attended the [April 13, 2005] meeting [with ECAC] because the Company's usual liaison with the FDA could not make it." SAC ¶ 43(f). As such, CW 6 clearly had no basis to form an opinion regarding the need for additional testing on Velac prior to April 13, 2005, and to the extent he formed such an opinion after the April 13, 2005 meeting, there is no allegation that it was ever communicated to any of the defendants. *See Wietschner v. Monterey Pasta Co.*, 294 F. Supp. 2d 1102, 1112-1113 (N.D. Cal. 2003) (holding that plaintiff must allege confidential witness has personal knowledge of facts to support statement because otherwise allegations amount to "unfounded and sometimes unintelligible speculation").

[16] Plaintiff also continues to base its claim on alleged negative statements by Connetics' panel of experts regarding Velac's prospects for approval. SAC ¶ 96. However, there are no facts regarding who heard the alleged statement or who on the expert panel made the statement. Moreover, even if plaintiff could amend its generalized allegations with the necessary particularity, this Court has already held that those allegations are insufficient to establish scienter. Order at 14.

drug, and without more does not demonstrate that defendants genuinely lacked the belief that such problems could be overcome. *See id.* (collecting cases).

The Ninth Circuit has rejected claims virtually identical to plaintiff's new allegations regarding the timing of FDA approval. In *In re Syntex Corp. Sec. Litig.*, 95 F.3d 922 (9th Cir 1996), for instance, the plaintiff alleged that Syntex's projections of FDA approval by a specific date were false because it was aware of undisclosed deficiencies in testing procedures for the new drug. The Ninth Circuit held:

> In estimating a date for FDA approval . . ., Syntex was making a prediction far in advance, while the drug was still in the testing stage, about an approval decision that lies in the hand of a regulatory body. . . . Any alleged deficiencies in the testing procedures do not indicate that Syntex's prediction of an FDA approval date was false when made. Instead, the company could have known of problems in the testing procedures, planned to remedy those deficiencies, and still thought it would achieve FDA approval by the estimated date.

Id. at 930. That holding applies here. *See also Ronconi*, 253 F.3d at 434 ("Problems and difficulties are the daily work of business people. That they exist does not make a lie out any of the alleged false statements"); *In re CBT Group PLC Sec. Litig.*, 1999 WL 1249287, at *3 (N.D. Cal. July 21, 1999) ("[E]ven if a company knows that a problem exists, it could still honestly and in good faith report that the company will continue to perform as expected. Management simply may have been confident that they could overcome the problems or merely underestimated the severity of such problems.").[17]

Plaintiff's claim of actual knowledge is also irreconcilable with the concrete business decisions Connetics made in preparation for the launch of Velac. Among other things, Connetics (1) committed significant time and resources to preparing and filing the Velac NDA and made a $3.5 million payment to Yamanouchi in connection with that filing, (2) hired and trained dozens

[17] Plaintiff's new focus on the Velac vehicle adds nothing to its claim. As an initial matter, plaintiff's allegation is not pled with any factual particularity, nor is it supported by the conclusory description of the Tg.AC test results found in the SEC complaint. *See* Declaration of Christopher J. Steskal In Support of Motion to Strike, Ex. 1 ¶ 20. In any event, according to plaintiff, Velac's vehicle was "critical to the efficacy" of Velac. SAC ¶ 72. Given that fact, defendants could reasonably conclude that the FDA would determine that the benefits of the vehicle far outweighed any risks associated with the positive response in the Tg.AC study. That is particularly true because, as discussed, the FDA had approved other acne products where an ingredient "critical to the efficacy" of the product (*e.g.*, benzoyl peroxide) had tested positive in the Tg.AC study.

of sales people (more than doubling its sales force) in Q4 2004, (3) prepared for commercial operations to manufacture, distribute, and sell Velac if and when it was approved, and (4) prepared the manufacturing site for FDA inspection. *See* SAC ¶¶ 223, 226, 241; Exs. 1, at 25, 13. It strains credulity that defendants would make these fundamental business decisions and invest significant resources, knowing all the time that the Velac NDA was deficient and that Velac could not be approved without additional testing. *See In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1118 (9th Cir. 1989) (scienter dispelled by decision to pour "millions of dollars into product development, market research and promotions").[18]

2. Plaintiff Cannot Overcome The Protections Of The Safe Harbor

Plaintiff also cannot state a claim based on forward-looking projections regarding the timing of Velac's approval and future revenue from Velac because those statements were accompanied by "meaningful cautionary language." 15 U.S.C. § 78u-5(c)(1)(A)(i). Whenever it made such projections, Connetics identified the projections as forward-looking and repeatedly advised that: (1) Velac may not be approved, (2) Velac may not be approved in the time frame projected, (3) the FDA may interpret the test data differently than Connetics, and (4) failure to obtain approval may adversely affect future revenue growth. *See* Ex. 50. Where, as here, the cautionary language warned of the actual risk that materialized, the safe harbor rule plainly applies, irrespective of any allegations of scienter. *See Olkey v. Hyperion 1999 Term Trust*, 98 F.3d 2, 5 (2d Cir. 1996) (plaintiffs' claim that cautionary language is boilerplate failed because "[t]he prospectuses warn investors of exactly the risk the plaintiffs claim was not disclosed").[19]

[18] *See also In re Praecis Pharms., Inc. Sec. Litig.*, 2007 WL 951695, at *12 (D. Mass. Mar. 28, 2007) ("it is not reasonable to think that the defendants intentionally launched the Company's flagship product with what they recognized was a flawed pricing structure, as if they were more interested in fooling the stock market in the short term than succeeding in the product market in the long run"); *Oppenheim Pramerica Asset Mgmt. S.A.R.L. v. Encysive Pharms., Inc.*, 2007 WL 2720074, at *5 (S.D. Tex. Sept. 18, 2007) (holding that company's investment of "significant resources in the development of [a drug], indicate[s] its genuine belief that the drug would receive FDA approval and be successfully marketed").

[19] *See also Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, 2005 WL 4161977, at *8-9 (D. Colo. Oct. 20, 2005) (holding that statements regarding the likelihood of FDA approval were barred by the safe harbor because "plaintiff does not allege that the defendants explicitly assured investors that FDA approval would soon be obtained… Projections about the likelihood of FDA approval are forward-looking statements. They are assumptions related to the Company's plan for its product, and as such fall under the PSLRA's safe harbor rule."); *GIA-GMI, LLC v. Michener*,

For example, plaintiff alleges that Connetics' projections of 2005 revenue were misleading because they were allegedly based on the expectation that Velac would be approved. SAC ¶ 254; Ex. 14 (Form 8-K). However, those projections were plainly identified as forward-looking and expressly incorporated the meaningful cautionary language contained in the Form 10-K, including:

> ***We may spend a significant amount of money to obtain FDA and other regulatory approvals, which may never be granted. Failure to obtain such regulatory approvals could adversely affect our prospects for future revenue growth.*** Successful product development in our industry is highly uncertain, and the process of obtaining FDA and other regulatory approvals is lengthy and expensive. Very few research and development projects produce a commercial product. . . . The FDA approval processes require substantial time [and] effort. . . . [W]e may not be able to obtain FDA approval to . . . manufacture and market any of the products we develop . . . Clinical trial data can be the subject of differing interpretation, and the FDA has substantial discretion in the approval process. The FDA may not interpret our clinical data the way we do.

Ex. 6, at 23 (2004 Form 10-K) (emphasis in original).[20] As such, Connetics plainly told investors that its future revenue growth could be adversely affected if drug candidates such as Velac were not approved and cautioned that the FDA approval process is extremely risky and uncertain. Because Connetics' projections regarding the timing of Velac approval and future revenue were accompanied by meaningful cautionary language, there can be no liability for those projections.[21]

2007 WL 2070280, at *30-31 (N.D. Cal. July 16, 2007) (claim barred where plaintiffs claim defendants falsely represented that a loan was "virtually certain," but defendants "expressly warned that [they] might not obtain [] financing…that there was no assurance [it] would be successful," and that they could not assure that they would "meet all of [the] conditions and that financing [would] close."); *In re Copper Mountain Sec. Litig.*, 311 F. Supp. 2d 857, 882 (N.D. Cal. 2004) (holding that cautionary statements in which "warnings included references to specific factors that were either the same or of similar significance to the actual causes of [the company's] downturn" were sufficient).

[20] Numerous courts have held that the cautionary language need not be contained in the same document as the disclosure, but may be incorporated by reference to Form 10-K filings and other documents. *See, e.g, In re ESS Tech., Inc. Sec. Litig.*, 2004 WL 3030058, at *30 (N.D. Cal. Dec. 1, 2004) (holding that press release could incorporate cautionary language from SEC filings); *In re Portal Software, Inc. Sec. Litig.*, 2005 WL 1910923, at *14 (N.D. Cal. Aug. 10, 2005) (same); *Copper Mountain*, 311 F. Supp. 2d at 876-82 (same); *In re Clorox Co. Sec. Litig.*, 238 F. Supp. 2d 1139, 1149 (N.D. Cal. 2002), *aff'd*, 353 F.3d 1125 (9th Cir. 2004) (holding that conference call could incorporate cautionary language from SEC filings); *In re Wet Seal, Inc. Sec. Litig.*, 518 F. Supp. 2d 1148, 1169 (C.D. Cal. 2007) ("It is also acceptable for a safe harbor provision in a press release or conference call to refer to SEC filings that may contain additional and more specific cautionary language").

[21] The Reform Act is clear that the safe-harbor rule applies to forward-looking statements in a press release or Form 8-K. There is no general exclusion that is applicable to SEC filings. *See* 15 U.S.C. § 78u-5(b)(2)(A) (exclusion limited to statements "included in a financial statement

B. Plaintiff Again Fails To Plead Particularized Facts Showing Either A Cogent And Compelling Inference Of Scienter Or Falsity With Respect To Any Other Statements

1. Plaintiff Cannot State A Claim With Respect To Connetics' Statements About The Status Of The Velac Program

Although hardly a model of clarity, plaintiff's complaint again appears to allege that any statement ever made by Connetics and its senior officers about the Velac program after June 2004 – regardless of the subject matter – was false and misleading because of the "omission" of any reference to the preclinical study. For example, plaintiff continues to challenge undeniably true statements, such as:

- "We concluded clinical trials in 2004 and subsequently submitted an NDA with the FDA for our product candidate Velac . . ." SAC ¶ 250.
- The Velac NDA was the company's "largest NDA filing to date" and "required a tremendous amount of work." *Id.* ¶ 231.
- Connetics paid a "$3.5 million milestone payment due to Yamanouchi Europe B.V. in conjunction with the submission of the Velac New Drug Application." *Id.* ¶¶ 223, 226.
- Connetics expanded the sales force in anticipation of a mid-year 2005 launch for Velac. *Id.* ¶¶ 241, 290.

Because none of these undeniably truthful statements had anything to do with the preclinical Tg.AC study, plaintiff's claim necessarily fails. *See Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002) (Rule 10b-5 does not contain "a freestanding completeness requirement" mandating disclosure of all details); *In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 268 (2d Cir. 1993) (rejecting argument that "whenever a corporation speaks, it must disclose every piece of information in its possession" on the topic); *In re Alkermes Sec. Litig.*, 2005 WL 2848341, at *16 (D. Mass. Oct. 6, 2005) ("when revealing facts such as a submission of an NDA, a company need not reveal all others that, too, would be interesting," but must only disclose those that would render an affirmative statement misleading).[22]

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prepared in accordance with generally accepted accounting principles"). The decision in *Baker v. MBNA Corp.*, 2007 WL 2009673 (D. Del. July 6, 2007), is contrary to the plain language of the statute.

[22] Plaintiff also cannot plead a claim based on statements made by third-party analysts. *See, e.g.*,

2. Plaintiff Cannot State A Claim With Respect To Connetics' Statements Regarding The Phase III Clinical Trials

As this Court has already ruled, any statement made prior to June 2004 – the date that Connetics allegedly received the results of the Tg.AC study – cannot be false or misleading, including Connetics' March 2004 announcement regarding the results of Phase III clinical trials involving over 2,200 patients.[23] Order at 12. Nonetheless, plaintiff now argues that Connetics' admittedly true statements regarding the Phase III clinical trials became intentionally "false and misleading" when Connetics filed its 2004 Form 10-K in March 2005 and expressly referenced the earlier press release and repeated the language of that press release virtually verbatim. SAC ¶ 250. Plaintiff bears a heavy burden under *Tellabs* to assert such a claim. Where, as here, plaintiff's theory rests on an alleged omission, plaintiff must plead facts to demonstrate that "the adverse facts were intentionally omitted" and that it is "more probable than not that the omission was for the purpose of deceiving, manipulating or defrauding the market." *Praecis Pharms.*, 2007 WL 951695, at *18. Whatever quarrels plaintiff may now purport to have with Connetics' disclosure concerning Phase III clinical trials, it fails to allege specific facts creating a "cogent and compelling" inference that Connetics intentionally omitted information about the Tg.AC study from its 2004 Form 10-K (or thereafter) for the purpose of deceiving the market.

As this Court has already recognized, the FDA's prior approval of other dermatological products that tested positive in the Tg.AC mouse model provided defendants with ample grounds to believe that Velac was "safe and effective" as demonstrated by the Phase III clinical trials. Order at 14. Other courts have reached the same conclusion. For example, in *Vertex*, the plaintiff

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SAC ¶¶ 86, 113-14, 252, 256, 257, 259. Plaintiff does not plead any facts suggesting that any defendant "adopted, endorsed or sufficiently entangled itself" with such statements, dooming any attempt to make defendants liable for them. *In re Syntex Corp. Sec. Litig.*, 855 F. Supp. 1086, 1097 (N.D. Cal. 1994), *aff'd*, 95 F.3d 922 (9th Cir. 1996); *see also In re Stac Elec. Sec. Litig.*, 89 F.3d 1399, 1410 (9th Cir. 1999) (defendants cannot be held liable for analyst statements unless specific facts are pled showing that they "put their imprimatur, express or implied" upon them); *In re Harmonic, Inc. Sec. Litig.*, 163 F. Supp. 2d 1079, 1094-95 (N.D. Cal. 2001) (same).

[23] In that announcement, Connetics accurately and truthfully disclosed that the Phase III clinical trial results demonstrated (1) "a consistently robust and statistically superior treatment effect for Velac compared with clindamycin gel, tretinoin gel and placebo gel;" (2) that Velac "was safe and well tolerated" by patients; and (3) that "the most commonly observed adverse effects [were] application site reactions (*e.g.*, burning dryness, redness and peeling)." Ex. 10 (Form 8-K).

alleged that defendants made false and misleading statements by providing "rosy statements about the progress of [Phase I and II] clinical trials" while failing to disclose that preclinical animal tests showed that the drug was "dangerously toxic." The court dismissed plaintiff's complaint:

> [T]he allegation that the defendants were aware that preclinical testing demonstrated a toxicity problem with VX-745 by March of 1999 is not in itself sufficient to demonstrate scienter. The fact that a drug has a certain toxicity level does not necessarily doom the drug's commercial prospects. As defendants point out, many drugs currently on the market are toxic depending on dosage levels and concentrations. Defendants note that other drugs (such as Lipitor and Zocor) have been found in animal studies to have toxic effects on the CNS in certain dosages, yet have been approved by the FDA. *See Def.'s Exh.* I, J. Thus, defendants' knowledge of some toxicity in VX-745 in 1999, without more, is insufficient to indicate "a mental state embracing intent to deceive, manipulate, or defraud."

357 F. Supp. 2d at 352-53 (citation omitted). The same analysis applies here. Because the FDA has determined that other dermal products that tested positive in the Tg.AC mouse model were "safe and effective" and thus could be marketed to consumers, defendants reasonably concluded that Velac was likewise "safe and effective" and that the positive response in the Tg.AC mouse model did not qualify or otherwise limit the undeniably excellent results of Phase III clinical testing.

This Court has also recognized that plaintiff cannot allege a "cogent and compelling" inference of scienter "because during this time period defendants had not heard anything from the FDA indicating that the FDA had concerns about the results of the transgenic mouse model." Order at 14. The absence of any negative comments by the FDA either before or after the filing of the NDA in August 2004 gave defendants even more reason to believe that Velac was "safe and effective" as demonstrated by the Phase III clinical trials. In fact, even in cases where the FDA has directly raised concerns about the approvability of a drug, courts have routinely held that defendants are not required to disclose those concerns or revise their opinion about the drug's efficacy or safety. *See, e.g., Noble Asset Mgmt.*, 2005 WL 4161977, at *7 ("fact that the FDA staff members raised questions did not impose a duty upon the defendants to revise their opinions about the drug's efficacy or to report to the public the substance of their conversations with the

FDA").[24] Where, as here, the FDA raised ***no*** concerns with Connetics about Velac or the Tg.AC study prior to April 13, 2005, there can be no claim that defendants intended to deceive when Connetics accurately reported the excellent results of the Phase III clinical trials.

The law is also clear that positive statements regarding one set of test results are not rendered knowingly misleading simply because defendants are aware of adverse results in a different study. *See In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 38, 40-42 (2d Cir. 2000) (holding that statements touting drug's "unprecedented safety profile" and lack of side effects were not misleading even though defendant had received "fifty-seven adverse medical reports," including reports of deaths); *DeMarco*, 149 F. Supp. 2d at 1223-24 (holding that positive statements regarding "safety and efficacy" were not misleading where defendants were aware of adverse test results); *MedImmune*, 873 F. Supp. at 966 (holding that statements regarding efficacy of drug were neither false nor misleading where FDA raised questions about test results and efficacy of drug); *see also Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 53 (2d Cir. 1995) ("mere allegations that statements in one report should have been made in earlier reports do not make out a claim of securities fraud"). There is absolutely no authority for the proposition that a drug sponsor must disclose every negative preclinical test result whenever it accurately describes the results of clinical trials in humans. To the contrary, the law is clear that there is simply no duty to disclose preclinical study results, or even communications with the FDA about such results.[25]

Plaintiff's claim that Connetics intended to mislead investors when it accurately described the results of the Phase III clinical trials is also undermined by the fact that the Tg.AC study is not always a reliable indicator of risk to humans and is known to have a high rate of "false positives."

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[24] *See also DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1224 (S.D. Cal. 2001) (undisclosed statements by FDA advisory committee about product's toxicity did not foreclose finding by FDA that product was safe and effective); *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Mere questioning by the FDA imposed no duty upon Defendants either to trim back their opinions as to the efficacy of the drug or to report to the public the FDA staffers' questions as they arose").

[25] *See Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988) (no liability absent a legal duty to speak); *see also Syntex*, 95 F.3d at 930 (no duty to disclose testing deficiencies); *Acito*, 47 F.3d at 53 (no duty to disclose plant deficiencies identified by FDA); *Alkermes*, 2005 WL 2848341, at *16 (no duty to disclose FDA request for further studies); *MedImmune*, 873 F. Supp. at 968 (no duty to disclose FDA questions regarding drug under review).

See supra at II.A.4. Defendants had no obligation to scale back or qualify their accurate description of the Phase III clinical trial results based on a test result in laboratory mice that was inconclusive at best, particularly where (as here) the FDA had determined that other products that had tested positive in the Tg.AC model were sufficiently safe to be approved for use by the general population. *See Carter-Wallace*, 220 F.3d at 42 (holding that statements regarding "unprecedented safety profile" were not intentionally misleading where defendant was aware of undisclosed negative data relating to safety; "the early medical reports may have indicated a potential problem, but . . . we would not expect Carter-Wallace to abandon its product on what, at the time, would have been speculation"). The fact that the FDA ultimately disagreed with defendants and did not approve Velac "does not mean that the defendants' statements about the results or design of the study were false. The plaintiff's characterization of the defendants' statements as misleading falls into the category of 'fraud by hindsight.'" *Noble Asset Mgmt.*, 2005 WL 4161977, at *11; *see also MedImmune*, 873 F. Supp. at 966 (holding that although "[m]edical researchers may well differ… in the interpretation of test results," such disagreement does not support an inference of scienter by a drug company).[26]

3. Plaintiff Cannot State A Claim With Respect To The Alleged Opinion Regarding The Ability Of Velac To Compete

Plaintiff has not alleged any facts creating a cogent and compelling inference that defendant Wiggans intended to deceive shareholders when he expressed his opinion that Connetics had "excellent data on Velac" and that "it's one of the strongest data sets for an acne product submitted to the FDA." SAC ¶¶ 241, 243. Instead of alleging particular facts establishing the necessary inference of scienter, plaintiff wrongly attributes the statements to Mr. Vontz and then takes the statements out of context by intentionally deleting sections in an

[26] *See also DeMarco*, 149 F. Supp. 2d at 1225 ("Although Plaintiffs may have established a legitimate difference in opinion as to the proper statistical analysis, they have hardly stated a securities fraud claim"); *Padnes v. Scios Nova Inc.*, 1996 WL 539711, at *4 (N.D. Cal. Sept. 18, 1996) ("The fact that plaintiffs disagree with the Colorado researchers and with defendants about the import of the Colorado data does not make defendants' summaries of the study false or misleading. The court finds that defendants' statements were within the realm of permissible judgment.").

effort to make it appear that Mr. Wiggans was discussing issues relating to safety.[27] In fact, Mr. Wiggans was merely offering an opinion on the ability of Velac to ***compete*** against other acne products.[28] The Court should reject plaintiff's attempt to rewrite the actual statements by making self-serving edits. *See Osher v. JNI Corp.*, 308 F. Supp. 2d 1168, 1186 (S.D. Cal. 2004), *aff'd in relevant part*, 183 Fed. Appx. 604 (9th Cir. 2006) (court must consider full document, not just portions plaintiff "selectively quotes"). When read in total, Mr. Wiggans' statements demonstrate that he was providing an accurate and good faith view on the prospective competitiveness of Velac. Plaintiff has not alleged any facts suggesting otherwise.

In any event, even if the statements were analyzed out of context, plaintiff has not alleged facts giving rise to a cogent and compelling inference of scienter. Mr. Wiggans' opinion that Velac was one of the "strongest data sets for an acne product" was supported by, among other things, the excellent Phase III clinical trial results, the large number of products that had been approved despite a positive response in animal carcinogenicity studies, the absence of any negative comments by the FDA regarding the Velac NDA, and the high number of "false positives" associated with the Tg.AC study. *See DeMarco*, 149 F. Supp. 2d at 1224 (rejecting plaintiff's theory of scienter where it "improperly ignore[s] numerous contemporaneous facts that provided ample factual support" for defendants' confidence in the data set). The mere fact that others might ultimately disagree with Mr. Wiggans does not mean that he acted with the intent to deceive when he formulated his opinion. *See Praecis Pharms.*, 2007 WL 951695, at *12 n.14 ("Assuming it to be true that the source had so 'informed management,' [that the pricing structure

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[27] *Compare* SAC ¶ 241 ("We have excellent data on Velac") with Ex. 2, at 3 ("But as we prepare . . . for our Velac launch our planning case is that there will be a competitive product for Velac but we have excellent data on Velac . . . .").

[28] Ex. 2, at 3 (Conference Call Tr.) ("our planning case is that ***there will be a competitive product for Velac*** but we have excellent data on Velac, we have now an expanded and very talented sales force, and we are confident that we will be successful in this market with our acne franchise and in particular with Velac") (emphasis added); *id*. at 17-18 (Q: "[W]hat is your current understanding of the status of any ***potential competitors to Velac*** . . . [and] your internal plan for such a competitor?" A: "[W]e know a lot about our product and that's all we know anything about frankly and we're very confident in the data set that we've got. We believe it's one of the strongest data sets for an acne product submitted to the FDA … I have a lot of confidence in the strength of our data. I've got a lot of confidence in the strength of our sales force and although we have anticipated in our A scenario if you will a competitor in the market we continue to believe we'll be very successful with our product.") (emphasis added).

was significantly flawed] more than that would be needed to support an allegation that 'management' itself knew the structure to be flawed, as opposed to knowing simply that someone else . . . thought that to be the case."); *Vertex Pharms.*, 357 F. Supp. 2d at 352 ("knowledge of some toxicity . . . without more, is insufficient to indicate 'a mental state embracing intent to deceive, manipulate, or defraud'"); *Bailey v. Eli Lilly Co.*, 607 F. Supp. 660, 662 (M.D. Penn. 1985) (stating that what "constitutes an 'adequate preclinical' test" is highly judgmental, and the FDA has approved drugs based on "the same application with the same tests [that] had allegedly previously been rejected by the FDA").[29]

4. Plaintiff Cannot State A Claim With Respect To Connetics' April 26, 2005 Form 8-K

As with its earlier complaint, plaintiff continues to allege that Connetics' Form 8-K providing an update on the regulatory status of Velac was false and misleading because it did not report ECAC's alleged statement that the Tg.AC test results were a "serious issue." SAC ¶ 108. However, plaintiff does not allege any facts establishing that any defendant was present for the ECAC call or made aware of the putative statement.[30] The only witness cited by plaintiff who was allegedly present during the conference call – CW 6 – does not identify a single defendant as a participant in the call or as otherwise privy to ECAC's alleged statement. In fact, CW 6 reports that ECAC only said that the test results "***'may be a problem,'***" and does not indicate whether,

[29] Moreover, the law is clear that generalized assertions of corporate optimism (*e.g.*, "excellent results," "one of the strongest data sets") are too vague and unspecific to be actionable under the securities laws. *See In re Cornerstone Propane Partners, L.P. Sec. Litig.*, 355 F. Supp. 2d 1069, 1087 (N.D. Cal. 2005) (statements such as "excellent results" and a "blowout winner product" are "mere puffery" and cannot constitute an actionable material misstatement); *Nathenson v. Zonagen Inc.*, 267 F.3d 400, 419 (5th Cir. 2001) (statements that that Phase III results are 'positive' are general statements that are "precisely the type of 'puffery' that this and other circuits have consistently held to be inactionable").

[30] Plaintiff resorts to blanket inferences based on the positions of defendants, their membership on the company's executive committee, and the importance of Velac to the company. *See, e.g.*, SAC ¶¶ 312-15. Such allegations are not enough to plead scienter. *See Vantive*, 283 F.3d at 1087-88 (defendants' knowledge not adequately established by allegations of "hands-on" management style or "attendance at meetings"); *In re Read-Rite Corp. Sec. Litig.*, 115 F. Supp. 2d 1181, 1183 (N.D. Cal. 2000), *aff'd*, 335 F.3d 843 (9th Cir. 2003) (holding that plaintiff cannot plead scienter based on assumption that persons with defendants' job titles and duties should have known of facts in question). Plaintiff's allegation that "on information and belief" Dr. Krochmal participated in the ECAC call (SAC ¶ 108) is bereft of any factual support.

when, or by whom this was communicated to defendants. SAC ¶ 43(f) (emphasis added). Plaintiff's allegations fall far short of a "cogent and compelling" inference that defendants omitted that alleged statement from the Form 8-K for the purpose of deceiving, manipulating, or defrauding the market. *See, e.g., See Silicon Graphics*, 183 F.3d at 985 (holding that plaintiff must allege particularized facts demonstrating that defendants were aware of alleged problems at the time allegedly false statements were made); *Tripp*, 2007 WL 4591930, at *3 (same); *Sanofi-Synthelabo Inc. v. Eastman Kodak Co.*, 2000 WL 1611068, at *11 (S.D.N.Y. Oct. 27, 2000) (same).

In any event, even if plaintiff's allegations regarding ECAC's statements are taken at face value, the facts nonetheless demonstrate that defendants acted in good faith and with the intent to update the market on Velac's regulatory status, not to deceive it. Plaintiff's claim turns on the inherently illogical proposition that Connetics voluntarily decided to share information with the market, yet deliberately decided to tell half-truths.[31] Not surprisingly, plaintiff's theory is unsupported by any facts creating a cogent and compelling inference that defendants did not actually believe that the disclosure was fair and reasonable. In fact, Connetics' decision to make a voluntary disclosure – instead of remaining silent – negates any cogent and compelling inference of scienter, even if plaintiff now quibbles about whether the phrase "serious issue" should have been included in the disclosure. *See Brody*, 280 F.3d at 1006 ("[n]o matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not"); *In re Guidant Corp. Sec. Litig.*, 2004 WL 2538374, at *16 (S.D. Ind. Nov. 8, 2004) ("voluntary disclosures of negative information," including information regarding communications with regulators, found to preclude a strong inference of scienter); *Shuster v. Symmetricom*, 2000 WL 33115909, at *7 (N.D. Cal. Aug. 1, 2000) ("courts do not presume that corporate officers make false statements simply out of spite or to impress others").

Connetics' decision to make the disclosure on Form 8-K also refutes any cogent and compelling inference of scienter. By statute and regulation, Form 8-K may be used by issuers to

[31] As shown above, there is no duty to disclose communications with the FDA about test results. *Supra* n.25.

disclose "material changes" in operations or events that the issuer "deems of importance to security holders." *See, e.g.*, Ex. 15 (Form 8-K disclosing comment under "Item 8.01"); Ex. 20, at 20 (instructions for filing Form 8-K under Item 8.01); 15 U.S.C. § 78m(l) (disclosure of "material changes"). Given the statutory and regulatory backdrop for Form 8-K disclosures, defendants reasonably believed that they were disclosing a potentially material or important issue when Connetics reported on Form 8-K that, among other things, (1) a preclinical study for carcinogenicity resulted in a "positive response," (2) Connetics and the FDA disagreed over the interpretation of the test results, (3) Connetics had been advised by a panel of experts that the positive response was the result of a limitation in the Tg.AC model, (4) the FDA had not raised this issue previously, and (5) discussions with the FDA were ongoing. *See* SAC ¶¶ 116-117; Ex. 15 (Form 8-K); Ex. 1, at 5-6 (analyst call transcript). After the disclosures, Connetics stock dropped, and analysts predicted a delay in approval, indicating that the market understood the potential seriousness of the issue. *See supra* at 11.[32]

Plaintiff's claim also ignores the fact that ECAC is only one of several advisory committees and that its views are not binding on the FDA. According to ECAC itself, its reports are advisory in nature and "***should not be interpreted by the sponsor as a measure of the approvability of their application***." Ex. 27 (FDA Manual § 7412.2) (emphasis added). Even if ECAC raised concerns about the Tg.AC study results, defendants knew that the FDA could still reject ECAC's views and decide that the benefits of Velac outweighed any purported risks. As shown above, defendants had ample reason to be optimistic about Velac's prospects for approval even after receiving ECAC's alleged comments, including the strength of the clinical trials and

[32] During the analyst call on the same day, Connetics also disclosed that approval might be delayed, and that it was unclear whether the FDA would require additional testing. *See* Ex. 1 at 10 ("[i]f there is a delay in that timeline there will be an impact on our financial forecast and we will update guidance accordingly"); *id*. at 18 ("We do not have 100% clarity on if there's any additional things we have to do."). Connetics also explained that "as a rule, we do not feel it is appropriate frankly, to provide regular updates on our discussions with [the] FDA. And we do not intend to provide further updates on this until we have more definitive information because obviously this is limited information for you and for us." *Id*. at 6; *see also Oppenheim*, 2007 WL 2720074, at *4 (no scienter where defendant's explanation of its reasons for not disclosing additional detail regarding communication with the FDA is cogent and compelling, and "it is as reasonable as Plaintiffs' belief that the decision to withhold those specifics constituted knowledge of some misstatement or omission").

the FDA's approval of other acne products that tested positive in the same test. Under these circumstances, defendants acted reasonably when they updated the market on Velac's regulatory status – namely, a disagreement with the FDA over how to interpret the positive response in the Tg.AC study – without expressly describing the issue as "serious" or otherwise speculating on how it might affect approvability. Courts have rejected claims in similar circumstances. *See Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894, 907 (N.D. Ill.), *aff'd*, 269 F.3d 806 (7th Cir. 2001) (rejecting disclosure claim where "Abbott was still negotiating with the FDA, and the FDA had not yet filed suit" and "Abbott expressed its opinion about its own compliance, but the risks were abundantly apparent on the statement's face"); *City Capital Assocs. Ltd. P'ship v. Interco, Inc.*, 696 F. Supp. 1551, 1556-57 (D. Del.), *aff'd*, 860 F.2d 60 (3d Cir. 1988) ("Where there exists a good faith dispute as to facts or an alleged legal violation, the [law] only requires disclosure of the dispute").[33]

5. Plaintiff's Miscellaneous Other Theories Of Scienter Are Deficient

a. The Insider Trading Allegations Refute Any Suggestion Of Scienter

There is nothing improper about an officer selling stock. *Vantive*, 283 F.3d at 1092. Only

[33] Plaintiff also incorrectly argues that defendants could not reasonably rely on the approval of benzoyl peroxide as indicative that Velac might be approved. SAC ¶¶ 122-25. First, the law is clear that the approval of other drugs with similar safety concerns refutes any inference of scienter in this case. *See Vertex*, 357 F. Supp. 2d at 352 (scienter negated by knowledge that other drugs with adverse effects had been approved by the FDA); *Citizens Comm'n on Human Rights v. FDA*, 1993 WL 1610471, at *2 (C.D. Cal. May 10, 1993), *aff'd*, 45 F.3d 1325 (9th Cir. 1995) (noting that "[o]nce an NDA has been approved, significant amounts of information summarizing the safety and effectiveness data submitted by the manufacturer and detailing the agency's bases for approval become available to the public"). Second, plaintiff's allegations relating to benzoyl peroxide are arguments, not facts. The law is clear that such arguments must be disregarded when determining whether a plaintiff has alleged sufficient facts to state a claim. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986) ("Although for the purposes of this motion to dismiss we must take all the factual allegations in the complaint as true, we are not bound to accept as true a legal conclusion couched as a factual allegation."); *Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994) (same); *Western Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981) (same); *Lee v. Bender*, 2005 WL 1388968, at *7 (N.D. Cal. May 11, 2005) ("Plaintiff's opinions and legal arguments are not 'factual' allegations that may be considered by this Court"). Third, even if plaintiff's arguments regarding benzoyl peroxide were treated as facts, plaintiff has not alleged that any of those "facts" was communicated to defendants or that defendants did not genuinely believe that benzoyl peroxide was a relevant comparable for Velac. Fourth, other products besides benzoyl peroxide have been approved by the FDA despite testing positive in carcinogenicity tests. Plaintiff just ignores them in the SAC.

allegations of "unusual" or "suspicious" insider trading during a class period can support a strong inference of scienter. *Ronconi*, 253 F.3d at 435. "[I]nsider trading is suspicious only when it is 'dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information.'" *Silicon Graphics*, 183 F.3d at 986, *quoting Apple*, 886 F.2d at 1117; *see also Ronconi*, 253 F.3d at 435. Here, plaintiff's allegations regarding defendants' trading continue to ***refute*** any inference of scienter as to both Velac and the alleged financial statement issues. *Vantive*, 283 F.3d at 1092, 1094 (stating "[i]nsider stock sales are not inherently suspicious" and holding defendant's non-suspicious sales tended "to negate such an inference.").

Plaintiff finally acknowledges – as it must – that Dr. Krochmal – Connetics' EVP of Research & Product Development – ***did not sell any shares whatsoever during the class period***. SAC ¶ 331. The utter absence of such sales by an officer who, according to plaintiff, was otherwise heavily involved in the efforts to obtain approval of Velac completely dispels the notion that defendants acted with scienter. Moreover, as demonstrated by Mr. Higgins' Forms 4 (Ex. 22), Mr. Higgins actually ***acquired*** more shares of Connetics' stock than he sold during the class period — once again negating any inference of scienter. *See In re Glenayre Techs. Inc. Sec. Litig.*, 1998 WL 915907, at *4 (S.D.N.Y. Dec. 30, 1998), *aff'd*, 201 F.3d 431 (2d Cir. 1999) ("one can assume that these high-ranking corporate officers, arguably the most knowledgeable . . . would be part of any fraudulent scheme to benefit from insider information through pre-emptive stock sales"); *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 540 (3d Cir. 1999) (no scienter where some defendants did not sell stock); *In re First Union Corp. Sec. Litig.*, 128 F. Supp. 2d 871, 899 (W.D.N.C. 2001) (lack of trading refutes scienter).[34]

The amount of shares sold by the other defendants is hardly suspicious or indicative of a scheme to defraud, since each retained the vast majority of his shares. *See* Ex. 49 (summarizing

[34] Plaintiff's vague allegation that Dr. Krochmal's stock options were "underwater" (SAC ¶ 331) is unsupported by particularized factual allegations, and in any event, is plainly wrong. As evidenced by Dr. Krochmal's Forms 4, Dr. Krochmal's stock options were "in-the-money" during most of the class period. *Compare* Ex. 24 *with* Ex. 49. Moreover, plaintiff's argument is legally irrelevant. *See Silicon Graphics*, 183 F.3d at 986-87 (court must consider all of defendant's "actual stock shares plus exercisable stock options").

defendants' stock sales and holdings). Dr. Krochmal, Mr. Vontz, Mr. Wiggans, and Mr. Higgins sold only 0%, 4.2%, 11.1%, and 17.8% of their respective holdings during the two and one-half year class period – well below amounts the Ninth Circuit has held are not exceptional. *See Vantive*, 283 F.3d at 1094 (noting that there is nothing "inherently alarming or unusual" about an insider selling "a quarter of his holdings over the course of fifteen months, particularly in a volatile industry"); *see also Ronconi*, 253 F.3d at 435; *Silicon Graphics*, 183 F.3d at 987. In addition, the alleged two-and-a-half year class period is so long that it is "difficult to see how particular stock sales would strengthen allegations that particular statements were uttered with deliberate recklessness at the times they were made." *Vantive*, 283 F.3d at 1093 (63-week class period).[35]

b. Plaintiff's Generic Allegations Of Other Motives Remain Insufficient To Establish Scienter

Plaintiff has done nothing to augment its other generic theories of scienter, which are little more than allegations that defendants were acting in a manner consistent with their duties as corporate executives. For instance, plaintiff maintains its charge that defendants engaged in fraud to complete a debt financing and receive an undefined benefit through a share repurchase program. *See* SAC ¶¶ 317-320. Such generalized allegations of motives have been repeatedly rejected as insufficient to show scienter. *Lipton v. PathoGenesis Corp.*, 284 F.3d 1027, 1036 (9th Cir. 2002) (alleged desire to obtain favorable financing is a normal corporate objective insufficient to allege scienter); *Marksman Partners L.P. v. Chantal Pharm. Corp.*, 927 F. Supp. 1297, 1310-12 (C.D. Cal. 1996) (motive to raise money in private placement insufficient); *Meyer v. Biopure*, 221 F. Supp. 2d 195, 209 (D. Mass. 2002) (same). Similarly, plaintiff's claim

[35] Furthermore, as is evident from the face of defendants' Form 4s, most of their sales were made pursuant to ***pre-arranged stock trading plans***. *See* Exs. 20-23 (Forms 4) ("Sale pursuant to plan adopted under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended."); 17 C.F.R. § 240.10b5-1 (describing plans). Rather than raise a strong inference of scienter, the use of these plans "raise an inference that the sales were pre-scheduled and not suspicious." *Wietschner v. Monterey Pasta Co.*, 294 F. Supp. 2d 1102, 1117 (N.D. Cal. 2003). Plaintiff completely ignored this fact in the AC, but now offers a newly-minted theory that these plans were adopted when certain defendants were in possession of "inside" information. SAC ¶ 330. This "new" tactic fails because plaintiff has not alleged any details regarding the alleged "inside" information, including what each defendant is alleged to have known and when.

that defendants were motivated by a desire to enhance their respective compensation packages (*see* SAC ¶¶ 321-342) has been repeatedly rejected as "a generic motive that could apply to any decision maker accused of participating in a securities fraud." *In re Carter-Wallace, Inc. Sec. Litig.*, 1999 WL 1029713, at *4 (S.D.N.Y. Nov. 10, 1999), *aff'd*, 220 F.3d 36 (2d Cir. 2000); *see also Acito*, 47 F.3d at 54; *In re Pfizer, Inc. Sec. Litig.*, ___ F. Supp. 2d ___, 2008 WL 540120, at * 8 (S.D.N.Y. Feb. 28, 2008); *Cutsforth v. Renschler*, 235 F. Supp. 2d 1216, 1250 (M.D. Fla. 2002).

V. PLAINTIFF HAS NOT CURED THE FUNDAMENTAL DEFICIENCIES PRESENTED BY ITS CLAIM RELATING TO CONNETICS' FINANCIAL STATEMENTS

A. Plaintiff Has Again Failed To Allege Facts Showing That Defendants Deliberately Misstated Financial Results

Plaintiff once again offers plenty of rhetoric in asserting that Connetics' modest restatement – which resulted in a total of just $1.1 million in adjustments in 2004 and $7.9 million in 2005 – was the product of "fraud" (SAC ¶ 191), but still has not identified concrete facts to back up that conclusion. Instead, plaintiff offers the same "very general allegations" that this Court previously found insufficient (Order at 20) and continues to suggest that the fact of a restatement is sufficient to allege scienter. SAC ¶¶ 185-192. As this Court has held, that is simply not the law. Order at 19 ("restatements and acknowledgements of GAAP violations are not enough to show scienter"); *see DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 390 (9th Cir. 2002); *In re Ramp Networks, Inc. Sec. Litig.*, 201 F. Supp. 2d 1051, 1060 (N.D. Cal. 2002). To state a claim, plaintiff must allege particularized facts that "(1) specific accounting decisions were improper; and (2) the defendants knew specific facts at the time that rendered their accounting determinations fraudulent." Order at 18 (citing *Morgan v. AXT, Inc.*, 2005 WL 2347125, at *14 (N.D. Cal. Sept. 23, 2005)). Plaintiff has once again failed to meet this burden.

Indeed, although there is no disagreement that Connetics determined that certain of its reserves needed to be restated because they had not adequately captured the potential for returns, rebates or chargebacks, plaintiff's SAC, like its predecessor, barely even mentions reserves, much

less pleads particularized, contemporaneous facts showing that defendants knowingly or deliberately set reserves at insufficient levels at the time. *Kane v. Madge Networks N.V.*, 2000 WL 33208116, at *5-6 (N.D. Cal. May 26, 2000), *aff'd sub nom.*, 3 Fed. Appx. 905 (9th Cir. 2002) ("plaintiffs must allege with particularity facts that show that the initial prediction was 'a falsehood'"). There is not a single allegation regarding what the reserves were in each period, what contemporaneous information existed establishing that the reserves in each period were inadequate and deliberately set too low, how any defendant was involved in or knew that the reserves were insufficient, or that any defendant had knowledge of accounting or the level of the reserves. *See Morgan*, 2005 WL 2347125, at *14 (plaintiff must allege facts showing "specific accounting decisions were improper" and that "defendants knew specific facts at the time that rendered their accounting determinations fraudulent").

Although plaintiff tries to distract from the absence of such facts with vague allegations of channel stuffing, it does not identify any "details as to specific shipments, customers, times, [and] dollar amounts related to the alleged channel stuffing" that the Court held was required. Order at 19-20. The SAC still does not offer the name of a single customer, the date or time of any shipment, or the dollar amounts of any transaction. Rather, it simply repeats the generalized allegation of "improper" shipments to meet quarter goals that this Court previously found deficient. *Id.*; *see In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1076 (N.D. Cal. 2001) (dismissing complaint with prejudice for failing to plead channel stuffing with sufficient particularity).[36]

Moreover, even assuming plaintiff had adequately alleged channel stuffing, it has failed to allege facts establishing that each defendant was aware that excess product was being sold and deliberately disregarded such information or otherwise acted with scienter. *See Tellabs*, 127 S. Ct. at 2510. For example, plaintiff's allegation that distributors "had nothing to lose by accepting

[36] *See Hockey v. Medhekar*, 30 F. Supp. 2d 1209, 1216 (N.D. Cal. 1998) (holding that "plaintiffs must identify the particular transactions underlying [the] alleged accounting deficiencies") (citation omitted); *In re DDi Corp. Sec. Litig.*, 2005 U.S. Dist. LEXIS 1056, at *64 (C.D. Cal. Jan. 7, 2005) (holding that plaintiff's allegations "fail to describe any particular transactions, precisely state when certain channel stuffing occurred, or, most importantly, indicate how much the channel stuffing skewed [defendant's] total results").

excess product because" they could return expired product "at the then-current sales price less 5%" (SAC ¶¶ 24, 168) falls far short of demonstrating that defendants "coerced its customers to accept more [product] than they wanted." *In re Sierra Wireless, Inc. Sec. Litig.*, 482 F. Supp. 2d 365, 376 (S.D.N.Y. 2007); *see also Greebel v. FTP Software, Inc.*, 194 F.3d 185, 202 (1st Cir. 1999) (coercive tactics are what distinguish so-called "nefarious channel stuffing from perfectly legitimate efforts to increase sales"). To the contrary, there simply are no allegations that Connetics had any ability to "coerce" its customers, which were large, powerful pharmaceutical distributors, much less that it engaged in some sort of improper quarter-end deal – for each and every quarter over two years – and that each defendant knew it.[37] Accordingly, plaintiff's theory hardly gives rise to a cogent and compelling inference that defendants were committing "fraud." *See Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1298 (9th Cir. 1998) (rejecting speculative channel stuffing claim made only in hindsight); *Greebel*, 194 F.3d at 202 ("[t]here is nothing inherently improper in pressing for sales to be made earlier than in the normal course").[38]

Plaintiff has also failed to ameliorate its other "very general allegations of scienter" which the Court previously found deficient. Order at 20. Plaintiff alludes to "forecast" and "internal" reports and unspecified "internal goals" (*see* SAC ¶¶ 165-76), but still fails to identify the date or contents of a single report containing historical prescription rates for any of Connetics' product; the date and content of sales forecasts; the amount by which particular sales forecasts allegedly exceeded the historical prescription data for each product; the amount of each product that was

[37] The general allegation that "distributors agreed to take excess product from Connetics because the company's prices for drugs were increasing by as much as 15-18% twice a year and distributors wanted to be able to buy at the lower price and then pass on the price increase to pharmacies" (SAC ¶ 43(c)) is unsupported by a single particularized fact to identify which drugs were sold to which customers, at which prices, and at which times. Moreover, by its terms, the allegation does not suggest channel stuffing but merely that distributors would want to buy low and sell high.

[38] Similarly, plaintiff's allegation regarding a "summer sizzle" sales promotion program which, as set forth in the SAC, was designed promote products with pharmacies and customers, who then ordered product from distributors (SAC ¶¶ 172-73), hardly suggests "channel stuffing." To the contrary, this is ordinary brand promotion. *See In re Bristol-Meyers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 566 (S.D.N.Y. 2004) ("Offering incentives to meet sales or earnings goals is a common practice, and, without additional allegations … the allegation that the sales at issue were made pursuant to incentives to meet goals set by management is an insufficient basis on which to infer conscious misbehavior or recklessness.").

allegedly improperly shipped in reliance on each sales forecast; who prepared each report; or who had access to each report. This is exactly the type of allegation that has been repeatedly rejected by the Ninth Circuit as insufficient. *Lipton*, 284 F.3d at 1036 (affirming dismissal where plaintiffs did not plead "in any detail, the contents of any such report or the purported data" regarding prescription rates and thus failed to establish basis for allegations that officers had knowledge of flat patient demand "that would cause their optimistic representations to the contrary to be consciously misleading") (internal quotation omitted); *Silicon Graphics*, 183 F.3d. at 985 (same); *In re Dreamworks Animation SKG, Inc., Sec. Litig.*, 2006 U.S. Dist. LEXIS 24456, at *15 (C.D. Cal. Apr. 12, 2006) (same); *Splash*, 160 F. Supp. 2d at 1070 (same).

Finally, plaintiff once again tries to avoid the inadequacies of its pleading by generally suggesting that reserves were set improperly to permit Connetics to meet earnings estimates. *See* SAC ¶¶ 321-27. Yet, plaintiff once again fails to identify any facts to suggest that anyone at Connetics manipulated or changed reserves in each of the eight quarters subject to the restatement to achieve this result, when or how they did this, or at whose direction. Moreover, the fact that (1) in three quarters, Connetics exceeded guidance even ***after*** the restatement (Q1 and Q2 of 2004, and Q3 of 2005); (2) in one quarter, Connetics did not meet guidance even ***before*** the restatement (Q4 of 2005); and (3) in two other quarters (Q2 of 2004 and Q2 of 2005), the effect of the restatement was to ***increase***, not decrease, Connetics' net revenue (that is, Connetics' reported net revenue was ***lower*** than it should have been),[39] negates any inference of scienter.[40]

[39] *Compare* Ex. 7, at F11-15 (Form 10-K/A) *with* Ex. 9 (Jan. 27, 2004 Form 8-K) (guidance for Q1 of 2004); Ex. 11 (May 4, 2004 Form 8-K) (guidance for Q2 of 2004); SAC ¶ 230 (guidance for Q4 of 2004); Ex. 13 (Jan. 25, 2005 Form 8-K) (guidance for Q1 of 2005); SAC ¶¶ 261, 264 (guidance for Q2 of 2005); Ex. 17 (Aug. 2, 2005 Form 8-K) (guidance for Q3 of 2005); AC ¶ 279 (guidance for Q4 of 2005).

[40] Unable to avoid this fundamental reality, plaintiff now offers a "new math" theory based on the broad and wholly unsupported proposition that although certain one-time charges and benefits are properly included for purposes of calculating earnings per share, analysts purportedly do not consider these items in assessing whether a company has met guidance. *See* SAC ¶¶ 325-26. Plaintiff then concludes that if these items were not included, for Q3 05 Connetics would have missed guidance before the restatement and for Q1 04 Connetics would still have met the Company's guidance. *Id*. Thus, even under plaintiff's "new math," there is still no pattern, much less one that gives rise to the "cogent and compelling" inference of scienter needed to plead securities fraud. *Tellabs*, 127 S. Ct. at 2510.

See Tellabs, 127 S. Ct. at 2510; *Gompper*, 298 F.3d at 897.[41]

B. Plaintiff Has Failed To Allege Loss Causation

Plaintiff cannot allege loss causation for the simple reason that Connetics' stock price ***increased*** after it announced on May 3, 2006 after the market closed that it would be restating its historical financial statements by approximately $8-9 million. *See Dura Pharms. Inc. v. Broudo*, 544 U.S. 336, 347 (2005) (plaintiff must allege that the "share price fell significantly after the truth became known" to the market); *In re Impax Labs Inc. Sec. Litig.*, 2007 WL 5076983, at *15 (N.D. Cal. Jan. 3, 2007) (plaintiff failed to show loss causation where stock price rose after announcement); *In re GlaxoSmithKline PLC Sec. Litig.*, 2006 WL 2871968, at *13 (S.D.N.Y. Oct. 6, 2006) (dismissing complaint where, as here, the complaint "fails to allege that a misrepresentation by Defendants, when revealed to the public, was the proximate cause of any loss suffered by Plaintiff.").

Unable to escape this fatal flaw, plaintiff offers the throwaway conclusion that "based on trading volume and price decline, the information in the press release leaked to the market prior to the close of trading." SAC ¶ 343(ii). Not surprisingly, plaintiff is unable to offer a single fact to support this speculation. Accordingly, since the dispositive question is how the market reacts to disclosure of the relevant truth, which occurred after the market closed on May 3, 2006, not at some earlier time before the disclosure was made, plaintiff has once again failed to plead loss causation. *See Dura*, 544 U.S. at 342-43.

Plaintiff is similarly unable to muster any new facts to plead loss causation with respect to Connetics' July 10, 2006 announcement. As a preliminary matter, since that announcement was

[41] The SAC also does nothing to cure the fundamental defects with respect to plaintiff's putative reliance on "confidential witnesses" to support its claims. Plaintiff still has not pled enough particularized detail "to support the probability that a person in the position occupied by the source would possess the information alleged." *In re Daou Sys. Inc. Sec. Litig.*, 411 F.3d 1006, 1016 (9th Cir. 2005). Indeed, there is still not a single allegation that any of the supposed "witnesses" worked in Connetics' finance or accounting department, had any involvement in or familiarity with the preparation of its financial statements or earnings releases, or any understanding of how Connetics was accounting for reserves or recognizing revenue. *See In re U.S. Aggregates, Inc. Sec. Litig.*, 235 F. Supp. 2d 1063, 1075 (N.D. Cal. 2002). Equally telling, the purported witnesses still ***do not provide any facts*** identifying particular products, when the shipments occurred, or any other specific details. *See Ramp*, 201 F. Supp. 2d at 1067.

made ***after*** the class period, plaintiff cannot base any loss thereon. *See Powell v. Idacorp*, 2007 WL 1498881, at *5 (D. Idaho May 21, 2007) ("because the misrepresentations were not made known to the marketplace until after the Class Period, the decline in stock price has not been causally linked to the improper activities of the Defendant").

More fundamentally, however, plaintiff still does not – and cannot – cite any previously undisclosed information in the July 10, 2006 announcement concerning Connetics' 2004 or 2005 reserves or financial statements. *See* SAC ¶ 127; Ex. 18 (Form 8-K); Ex. 19 (Form 8-K). Rather, the announcement indicated that Connetics was revising its forward-looking guidance because it had made the business decision to "ship below estimated prescription demand during the remainder of 2006" in order to reduce "average wholesaler inventory levels to approximately two months on hand by the end of 2006." SAC ¶ 182. In addition, the July 10 press release merely reiterates the exact same information in the May 3 press release regarding reserves in 2004 and 2005. Ex. 19. As such, loss causation is utterly lacking. *See Dura*, 544 U.S. at 343 (it is not enough for disclosure to "touch upon" the subject of alleged misrepresentation in some way; rather, the disclosure must reveal the "relevant truth" to have "caused" the loss); *In re IPO Sec. Litig.*, 399 F. Supp. 2d 298, 307 (S.D.N.Y. 2005), *aff'd sub nom.*, 2006 WL 1423785 (2d Cir. 2006) (same).[42]

VI. PLAINTIFF HAS AGAIN FAILED TO PLEAD A CLAIM UNDER SECTION 20A

Plaintiff purports to assert an insider trading claim under Section 20A of the 1934 Act against Mr. Wiggans, Mr. Vontz and Mr. Higgins (but not Dr. Krochmal, who is ***not*** alleged to have sold any Connetics stock). SAC ¶¶ 386-92. Section 20A requires, *inter alia*, an independent violation of the 1934 Act. *In re Verifone Sec. Litig.*, 11 F.3d 865, 872 (9th Cir.

[42] Finally, to the extent plaintiff purports to base its claim on supposed "channel stuffing," loss causation is absent because plaintiff can point to no disclosure, either by Connetics or a third party, suggesting that Connetics had sold unwanted product to its customers in 2004 and 2005. *See D.E.& J. Ltd. P'ship v. Conaway*, 133 Fed. Appx. 994, 1000-01 (6th Cir. 2005) (no loss causation based on stock price drop on announcement of bankruptcy since filing did not reveal prior alleged misrepresentation); *In re Tellium, Inc. Sec. Litig.*, 2005 WL 2090254, at *1 (D.N.J. Aug. 26, 2005) (no loss causation based on announcement of bad news that did not disclose defendants' fraud); *In re Avista Corp. Sec. Litig.*, 415 F. Supp. 2d 1214, 1219-20 (D. Wash. 2005) (dismissing complaint where disclosures that caused the stock price drop did not reveal prior misrepresentations).

1993). The Court previously dismissed plaintiff's claim under Section 20A for failure to plead an underlying claim under Section 10(b). Order at 22. Because plaintiff has again failed to plead an underlying violation of Section 10(b), it should do so again.

The claim also fails because, despite plaintiff's opportunity to amend, the complaint continues to lack particularized facts establishing that the defendants sold Connetics stock on the basis of material non-public information. *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993) (plaintiff must allege particularized facts specific to each defendant, including "the times, dates, places, benefits received, and other details of the alleged fraudulent activity"); *In re 3Com Corp. Sec. Litig.*, 1999 WL 1039715, at *3 (N.D. Cal. July 8, 1999) (same). Similarly, plaintiff does not even try to allege that it traded "contemporaneously" with Mr. Wiggans or Mr. Vontz. The Section 20A claim against them fails for that reason alone. *In re HI/FN, Inc. Sec. Litig.*, 2000 WL 33775286, at *12 (N.D. Cal. Aug. 9, 2000). With respect to Mr. Higgins, plaintiff purports to identify his sale of 5,000 shares of Connetics common stock on April 19, 2005. SAC ¶ 391. However, plaintiff does not provide any specifics concerning the alleged "inside information." Moreover, because plaintiff itself now concedes that the sale was made pursuant to a pre-existing trading plan under Rule 10b5-1 (Ex. 21-24 (Forms 4)), Mr. Higgins could not have been selling securities on the basis of material nonpublic information. *See Wietschner*, 294 F. Supp. 2d at 1117.[43]

VII. PLAINTIFF HAS AGAIN FAILED TO PLEAD A CONTROL PERSON CLAIM UNDER SECTION 20(A)

Because plaintiff has not pleaded a viable claim under Section 10(b), its control person claim under Section 20(a) against Mr. Wiggans, Mr. Vontz and Mr. Higgins necessarily fails. (There is no such claim brought against Dr. Krochmal.) The Court should once again dismiss the claim. *Paracor Fin., Inc. v. General Elec. Cap. Corp.*, 96 F.3d 1151, 1161 (9th Cir. 1996).

[43] Plaintiff's new assertion that the 10b5-1 plan was entered into while in possession of material non-public information is utterly unsupported by any particularized facts. Plaintiff does not allege details regarding the alleged "inside" information including what each defendant is alleged to have known and when. SAC ¶ 330. Accordingly, plaintiff has put forth no facts to rebut the inference that the 10b5-1 planned sales could not have been based on material nonpublic information.

The claim also fails because plaintiff has not pleaded facts showing that each defendant had "actual power" or "exerted" influence over the controlled person with respect to the specific transaction or activity upon which the alleged primary violation was predicated. *See Durham v. Kelly*, 810 F.2d 1500, 1503-04 (9th Cir. 1987); *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1067 (9th Cir. 2003); *In re Gupta Corp. Sec. Litig.*, 900 F. Supp. 1217, 1243 (N.D. Cal. 1994). For example, plaintiff still does not attempt to explain how Mr. Higgins, as CFO, could be responsible for or control the Company's disclosures concerning Velac or how Mr. Wiggans and Mr. Vontz, as CEO and COO respectively, were responsible for or controlled Connetics' accounting for reserves or other items. *See Howard*, 228 F.3d at 1067 (plaintiff "simply points to [defendants'] general level of control but provides no specific indication that [they] supervised or had any responsibility for the preparation of the financial statements"); *Gupta*, 900 F. Supp. at 1243 (it is not enough to allege their status as senior officers or claim that they signed SEC filings).

CONCLUSION

Despite having the opportunity to consider this Court's ruling and amend its pleading, plaintiff has once again failed to state a cognizable claim. Accordingly, for the foregoing reasons, the Second Amended Complaint should be dismissed with prejudice.

Dated: May 2, 2008

FENWICK & WEST LLP

By: /s/ Christopher J. Steskal
Christopher J. Steskal

Attorneys for Defendants Connetics Corp., John L. Higgins, Lincoln Krochmal, C. Gregory Vontz, and Thomas G. Wiggans